REMARKS

Reconsideration and withdrawal of the rejections of the application are respectfully requested in view of the amendments and remarks herewith and those of record, which are incorporated herein by reference, which place the application into condition for allowance or into better condition for appeal.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 7, 8, 10, 12-14, 16, 17, 19, 21-24 and 26-45 are pending. Claims 12, 19, 26-37 and 39, 40 and 42-44 are amended, claims 20 and 25 cancelled and new claim 45 added, without prejudice.

Attached hereto is a marked up version of the changes made to the claims and the specification by the present amendment. This attachment is captioned "Version with Markings Showing Changes Made."

No new matter is added by these amendments.

It is submitted that these claims are patentably distinct from the prior art cited by the Examiner, and that these claims are in full compliance with the requirements of 35 U.S.C. §112. The amendments are remarks herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112; but rather the amendments and remarks are made simply for clarification and to round out the scope of protection to which Applicants are entitled. Support for the amended recitations in the claims is found throughout the specification. More specifically, support for new claim 45 is found in claims 9 and 25.

II. 35 U.S.C. §112, FIRST PARAGRAPH, REJECTION

Claims 12-14, 16 and 17 were rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to convey that Applicants had possession of the claimed invention. The rejection is traversed.

The amendments to the claims, without prejudice, have rendered the rejection moot. Further still, the allegations that the specification does not clearly explain how the invention is made and used to obtain the claimed results are without merit. Possession clearly existed.

A lead case on the written description requirement is *In re Edwards*, 568 F.2d 1349 (C.C.P.A. 1970). The application of that case by the Federal Circuit is the state of the law on the issue. According to *Edwards*, the function of the written description requirement is to:

> [E]nsure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him; to comply with the description requirement, it is not necessary that the application describe the claimed invention in *ipsis verbis*; all that is required is that it reasonably convey to persons skilled in the art that, as of the filing date thereof, the inventor had possession of the subject matter later claimed by him.

(*Id.* at 1351-52) (emphasis added).

Thus, determining whether the written description requirement is satisfied requires reading the disclosure in light of the knowledge possessed by a skilled artisan. Such knowledge can be established by reference to patents and publications available to the public prior to the filing date of the application.

Applying the law to the instant facts, it is clear possession did exist at the time of filing. The present invention is directed to, *inter alia*, a method of detecting the presence or absence of bacteria comprising the steps of : (i) using a kit according to claims 26, 27, 28 or 29; (ii) carrying out nucleic acid hybridisation or nucleic acid amplification or nucleic acid hybridization plus

amplification and detecting the presence or absence of strains of *Pseudomonas aeruginosa*. A skilled artisan, reading the instant specification, particularly pages 16-21, would readily understand that possession existed for, *inter alia*, detecting the presence or absence of strains of *Pseudomonas aeruginosa*.

Consequently, reconsideration and withdrawal of the Section 112, first paragraph, rejection are respectfully requested.

III. 35 U.S.C. §103 REJECTION

Claims 7, 8, 10, 12-14, 16, 17, 19, 20, 22-25 and 26-41 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Accession Number Y00432. The rejection is traversed.

It is well-settled that there must be some prior art teaching which would have provided the necessary incentive or motivation for modifying the reference teachings. *In re Laskowski*, 12 U.S.P.Q. 2d 1397, 1399 (Fed. Cir. 1989); *In re Obukowitz*, 27 U.S.P.Q. 2d 1063 (BOPAI 1993). Further, "obvious to try" is not the standard under 35 U.S.C. §103. *In re Fine,* 5 U.S.P.Q. 2d 1596, 1599 (Fed. Cir. 1988). And, as stated by the Court in *In re Fritch*, 23 U.S.P.Q. 2d 1780, 1783-1784 (Fed. Cir. 1992): "The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggests the desirability of the modification." Also, the Examiner is respectfully reminded that for the Section 103 rejection to be proper, **both the suggestion of the claimed invention and the expectation of success must be founded in the prior art, and not Applicants' disclosure.** *In re Dow*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988).

The requisite suggestion or motivation is lacking in the document relied upon in the Final Office Action. More specifically, Applicants' invention is directed to, *inter alia*, isolated nucleic acid molecules, kits and methods of detecting the presence or absence of *Pseudomonas*

aeruginosa. Accession No. Y00432 does not teach, suggest, or motivate a skilled artisan to practice such an invention.

Furthermore, the instant invention exhibits unexpected results and superiority over the art and, thus, rebuts any holding of *prima facie* obviousness. As seen in Example 1 of the specification, eighty-six (86) different strains of *Pseudomonas aeruginosa* have been discriminated over thirty-one (31) strains of other species by utilizing Applicants' invention.

Therefore, even if it was so held that a person with ordinary skill in the art would have been motivated to practice the claimed invention in light of Accession No. Y00432, a point Applicants do not concede, the data in the specification clearly rebut such a holding since the prior publication does not suggest that the instant invention would exhibit such superior discrimination between strains of *Pseudomonas aeruginosa*. The claimed invention is, thus, unobvious.

Consequently, even if a *prima facie* case of obviousness were established, a point Applicants do not concede, the data in the specification clearly rebuts such a holding and the rejections of the claims should be removed accordingly.

Accordingly, reconsideration and withdrawal of the Section 103 rejections based on the preceding document are respectfully requested.

IV. 35 U.S.C. §112, SECOND PARAGRAPH, REJECTION

Claims 12-14, 16, 17, 26-30, 31, 33, 34, 36, 37, 39, 40, 42 and 43 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. The rejection is traversed.

The amendments to the claims, without prejudice, have rendered the instant rejection moot.

Consequently, reconsideration and withdrawal of the Section 112, second paragraph, rejection are respectfully requested.

V. 35 U.S.C. §102 REJECTION

Claims 30, 33, 36 and 39 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Accession No. X15400. The rejection is traversed.

It is respectfully pointed out that a two-prong inquiry must be satisfied in order for a Section 102 rejection to stand. First, the prior art reference must contain all of the elements of the claimed invention. *See Lewmar Marine Inc. v. Barient Inc.,* 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987). Second, the prior art must contain an enabling disclosure. *See Chester v. Miller,* 15 U.S.P.Q.2d 1333, 1336 (Fed. Cir. 1990). A reference contains an enabling disclosure if a person of ordinary skill in the art could have combined the description of the invention in the prior art reference with his own knowledge of the art to have placed himself in possession of the invention. *See In re Donohue*, 226, U.S.P.Q. 619, 621 (Fed. Cir. 1985).

Applying the law to the instant facts, Accession No. X15400 fails as evidence of anticipation. More specifically, the document relied upon by the Examiner neither discloses nor enables, *inter alia*, an isolated nucleic acid molecule as a component of a kit according to claim 26, comprising a nucleic acid sequence selected from the group consisting of SEQ ID No. 3, SEQ ID No. 4 and SEQ ID No. 5 and the complement of SEQ ID No. 3, SEQ ID No. 4 and SEQ ID No. 5, wherein said nucleic acid molecule is a shortened sequence as compared to that of SEQ ID No. 1.

Further still, Applicants disagree with the allegation on page 9 of the Final Office Action that Accession No. X15400 recites a sequence possessing at least 10 consecutive sequences of SEQ ID No. 3. Contrary to the Examiner's allegations, a comparison of the sequence listed in

Accession No. X15400 with SEQ ID No. 3 reveals that there is not more than 8 or 9, but not 10, shared consecutive sequences:

	CTT GGG CTT ACG TCT ATC CG	SEQ ID NO. 3
...	CCT GGG CTT AAG TCT ATC CG ...	X15400.

Thus, as the document relied upon in the Final Office Action does not teach and enable each and every feature of Applicants' invention, the Section 102(b) rejection must fail as a matter of law.

Consequently, reconsideration and withdrawal of the rejection is respectfully requested.

CONCLUSION

By this Amendment, the pending claims should be allowed; and this application is in condition for allowance or in better condition for appeal. Favorable reconsideration of the application, withdrawal of the rejections and objections, and prompt issuance of the Notice of Allowance are, therefore, all earnestly solicited.

Respectfully submitted,

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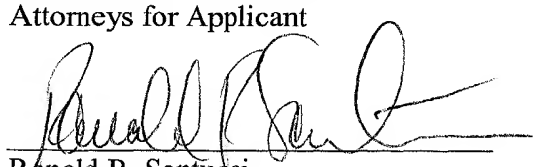
By: 

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VERSION TO SHOW CHANGES MADE

IN THE CLAIMS:

12. (Amended Twice) A method of detecting the presence or absence of bacteria comprising the steps of : (i) using a kit according to claims [11] 26, 27, 28 or 29; (ii) carrying out nucleic acid hybridisation or nucleic acid amplification or nucleic acid hybridization plus amplification and detecting the presence or absence of [bacteria belonging to a group of bacteria of the *Pseudomonas* genus] strains of *Pseudomonas aeruginosa*.

19. (Amended Twice) An isolated nucleic acid molecule according to claim [6] 30, wherein the nucleic acid sequence is from 15 to 30[,] nucleotides long.

26. (Amended) A kit for the detection of strains of *Pseudomonas aeruginosa*, comprising: (i) one or more nucleic acid molecules selected from the group consisting of: (a) an isolated nucleic acid molecule comprising a nucleic acid sequence selected from the group consisting of SEQ ID No. 3, SEQ ID No. 4 and SEQ ID No. 5 and the complement of SEQ ID No. 3, SEQ ID No. 4 and SEQ ID No. 5, wherein said nucleic acid molecule [comprises] is a shortened sequence as compared to that of SEQ ID No. 1.; (b) SEQ ID No. 1; and (c) SEQ ID No. 2; and (ii) optionally substances for analytical detection processes.

27. (Amended) A kit for the detection of strains of *Pseudomonas aeruginosa*, comprising: (i) one or more nucleic acid molecules selected from the group consisting of: (a) an isolated nucleic acid molecule comprising at least 10 contiguous nucleotides from a nucleic acid

sequence selected from the group consisting of SEQ ID No. 3, SEQ ID No. 4 and SEQ ID No. 5 and the complement of SEQ ID No. 3, SEQ ID No. 4 and SEQ ID No. 5, wherein said nucleic acid molecule [comprises a shorter sequence then] is a shortened sequence compared to that of SEQ ID No. 1; (b) SEQ ID No. 1; and (c) SEQ ID No. 2, and (ii) optionally substances for analytical detection processes.

28. (Amended) A kit for the detection of strains of *Pseudomonas aeruginosa*, comprising: (i) one or more nucleic acid molecules selected from the group consisting of: (a) An isolated nucleic acid molecule comprising at least 10 contiguous nucleotides [from] wherein said molecule corresponds in 9 out of 10 contiguous nucleotides to a nucleic acid sequence selected from the group consisting of SEQ ID No. 3, SEQ ID No. 4 and SEQ ID No. 5 and the complement of SEQ ID No. 3, SEQ ID No. 4 and SEQ ID No. 5, wherein said nucleic acid molecule [comprises a shorter sequence than] is a shortened sequence compared to that of SEQ ID No. 1 [and said 10 contiguous nucleotides correspond to said nucleic acid molecule in 9 out of 10 contiguous nucleotides]; (b) SEQ ID No. 1; and (c) SEQ ID No. 2; and (ii) optionally substances for analytical detection processes.

29. (Amended) A kit for the detection of strains of *Pseudomonas aeruginosa*, comprising: (i) one or more nucleic acid molecules selected from the group consisting of: (a) An isolated nucleic acid molecule comprising at least 10 contiguous nucleotides [from] wherein said molecule corresponds in 8 out of 10 contiguous nucleotides to a nucleic acid sequence selected from the group consisting of SEQ ID No. 3, SEQ ID No. 4 and SEQ ID No. 5 and the complement of SEQ ID No. 3, SEQ ID No. 4 and SEQ ID No. 5, wherein said nucleic acid molecule [comprises a shorter sequence than] is a shortened sequence compared to that of SEQ

ID No. 1 [and said 10 contiguous nucleotides correspond to said nucleic acid molecule in 8 out of 10 contiguous nucleotides]; (b) SEQ ID No. 1; and (c) SEQ ID No. 2; and (ii) optionally substances for analytical detection processes.

30. (Amended) An isolated nucleic acid molecule as a component of a kit according to claim 26, comprising a nucleic acid sequence selected from the group consisting of SEQ ID No. 3, SEQ ID No. 4 and SEQ ID No. 5 and the complement of SEQ ID No. 3, SEQ ID No. 4 and SEQ ID No. 5, wherein said nucleic acid molecule [comprises] is a shortened sequence as compared to that of SEQ ID No. 1.

31. (Amended) The isolated nucleic acid molecule according to claim 30, wherein the nucleic acid sequence contains 10 to [250 nucleotides] not more nucleotides than SEQ ID NO. 1.

32. (Amended) The isolated nucleic acid molecule according to claim 30, wherein the nucleic acid sequence contains 15 to 30[,] nucleotides.

33. (Amended) An isolated nucleic acid molecule as a component of a kit according to claim 27, comprising at least 10 contiguous nucleotides from a nucleic acid sequence selected from the group consisting of SEQ ID No. 3, SEQ ID No. 4 and SEQ ID No. 5 and the complement of SEQ ID No. 3, SEQ ID No. 4 and SEQ ID No. 5, wherein said nucleic acid molecule [comprises a shorter sequence then] is a shortened sequence compared to that of SEQ ID No. 1.

34. (Amended) The isolated nucleic acid molecule according to claim 33, wherein the nucleic acid sequence contains 10 to [250 nucleotides] not more nucleotides than SEQ ID NO. 1.

35. (Amended) The isolated nucleic acid molecule according to claim 33, wherein the nucleic acid sequence contains 15 to 30[,] nucleotides.

36. (Amended) An isolated nucleic acid molecule as a component of a kit according to claim 28, comprising at least 10 contiguous nucleotides [from] wherein said molecule corresponds in 9 out of 10 contiguous nucleotides to a nucleic acid sequence selected from the group consisting of [SEQ ID No. 3,]SEQ ID No. 4 and SEQ ID No. 5 and the complement of [SEQ ID No. 3,] SEQ ID No. 4 and SEQ ID No. 5, wherein said nucleic acid molecule comprises [a shorter sequence than] is a shortened sequence compared to that of SEQ ID No. 1 [and said 10 contiguous nucleotides correspond to said nucleic acid molecule in 9 out of 10 contiguous nucleotides].

37. (Amended) The isolated nucleic acid molecule according to claim 36, wherein the nucleic acid sequence contains 10 to [250 nucleotides] not more nucleotides than SEQ ID NO. 1.

39. (Amended) An isolated nucleic acid molecule as a component of a kit according to claim 29, comprising at least 10 contiguous nucleotides from a nucleic acid sequence selected from the group consisting of [SEQ ID No. 3,] SEQ ID No. 4 and SEQ ID No. 5 and the complement of [SEQ ID No. 3,] SEQ ID No. 4 and SEQ ID No. 5, wherein said

nucleic acid molecule comprises a shorter sequence than that of SEQ ID No. 1 and said 10 contiguous nucleotides correspond to said nucleic acid molecule in 8 out of 10 contiguous nucleotides.

40. (Amended) The isolated nucleic acid molecule according to claim 39, wherein the nucleic acid sequence contains 10 to [250 nucleotides] not more nucleotides than SEQ ID NO. 1.

42. (Amended) An isolated nucleic acid molecule as a component of a kit according to claim 45, comprising at least 10 contiguous nucleotides [from a nucleic acid sequence selected from the group consisting of SEQ ID No. 3, SEQ ID No. 4 and SEQ ID No. 5 and the complement of SEQ ID No. 3, SEQ ID No. 4 and SEQ ID No. 5], wherein said nucleic acid molecule [comprises a shorter sequence than] is a shortened sequence compared to that of SEQ ID No. 1 and said 10 contiguous nucleotides are at least 90% homologous to a nucleic acid sequence selected from the group consisting of [SEQ ID No. 3,] SEQ ID No. 4 and SEQ ID No. 5 and the complement of [SEQ ID No. 3,] SEQ ID No. 4 and SEQ ID No. 5 and said nucleic acid sequences [allows] allow for the detection of bacteria of the *Pseudomonas* genus by means of nucleic acid hybridisation or amplification.

43. (Amended) The isolated nucleic acid molecule according to claim 42, wherein the nucleic acid sequence contains 10 to [250 nucleotides] not more nucleotides than SEQ ID NO. 1.

44. (Amended) The isolated nucleic acid molecule according to claim 42, wherein the nucleic acid sequence contains 15 to 30[,] nucleotides.